Louisiana Medicaid
New Drugs Introduced into the Market / Non-Preferred

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred drugs without specific clinical criteria or new drugs introduced into the market prior to Pharmaceutical and Therapeutics (P&T) review.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations; refer to individual prescribing information for details.*

Any new drug introduced into the market, where the labeler participates in the drug rebate program, may be considered non-preferred and may require prior-authorization until the new drug is reviewed by the P&T Committee. The Drug Utilization Review (DUR) Board may review and recommend clinical criteria for the new drug. This policy is a default if no other criteria has been established through DUR.

Approval Criteria for Initial and Reauthorization Requests

- The requested drug is being used for an FDA-approved indication; **OR**
- The requested drug is being used for an indication cited by peer reviewed medical literature and is supported in one of the following compendia:
    - American Hospital Formulary Service (AHFS) Drug Information; **OR**
    - United States Pharmacopeia-Drug Information (USP-DI) or its successor publications; **OR**
    - DRUGDEX Information System; **AND**
- The requested quantity falls within the manufacturer's published dosing guidelines or within dosing guidelines found in AHFS, USP-DI or DRUGDEX; **AND**
- Previous use - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred drug that is appropriate to use for the condition being treated; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred drug that is appropriate to use for the condition being treated; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred drugs that are appropriate to use for the condition being treated; **OR**
    - There is no alternative preferred drug that is appropriate to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested

medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: Up to 6 months
An appropriate duration of initial authorization and reauthorization approval will be determined based upon patient-specific factors and the condition being treated.

Revision / Date	**Implementation Date**
Policy created / March 2019	March 2019
Removed FFS from title, added the word 'prior', clarified wording regarding use of other agents, removed footer, and added revision table / January 2020	January 2020
Formatting changes / December 2021	January 2022